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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,931	03/03/2000	Reiner L. Gentz	PF454P1	7173

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HUMAN GENOME SCIENCES INC
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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,931

Applicant(s)

GENTZ ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-88 and 102-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-88 and 102-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/11/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 24-88 and 102-131 are pending in the instant application. Claims 46, 61, 76, 102 and 124 have been amended as requested by Applicant in the Paper filed November 8, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 46-75, 102-116 and 124-125 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record in the previous office action mailed May 9, 2005, at pages 2-4. Applicants have canceled claims 117-123, so the rejection does not apply to those claims. Applicants have amended claim 124 to recite that the claimed polypeptide "binds Fas ligand", and believe that the present rejection has been overcome.

This amendment has been fully considered but is not found to be persuasive. The courts have specifically stated that the skilled artisan cannot envision the *detailed chemical structure* of an encompassed polypeptide until the structure is disclosed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In the instant case, SEQ ID NO: 2 has been

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disclosed, but no sequence variants thereof have been disclosed. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claims are a partial structure in the form of a recitation of percent identity and activity of binding Fas ligand. Although there is partial structure and activity claimed, the degree of structure is also important in determining possession. There is no identification of any particular portion of the structure that must be conserved in order to conserve the required function. Clearly, such does not constitute disclosure of a representative number of examples of, nor adequate written description for, the claimed genus.

Entitlement to Priority

3. Applicants disagree with the effective filing date of March 4, 1999, and submit that as stated As stated in M.P.E.P. §2107.02, "an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112...See, e.g., *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984) (When a properly claimed invention meets

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at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.'). Applicants assert that the claimed polypeptides have a specific and substantial utility, for example, in the treatment of graft vs. host disease, which utility is clearly disclosed in the present specification in the paragraph bridging pages 8 and 9, and in the earliest application to which the present application claims priority, namely Application Serial No. 60/035,496 filed January 14, 1997, in the second full paragraph on page 7. Applicants submit that this utility has been confirmed by Zhang et al., (of record), and that The Federal Circuit held in *In re Brana*, evidence dated after the filing date can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification." 51 F. 3d. 1560,

Applicants emphasize that the asserted utility in the present application is adequate under all applicable authority. Applicants' asserted utility is a specific, substantial and credible utility and not a "throw away" utility (such as using a composition for landfill as defined in the current United States Patent and Trademark Office's Utility Guidelines.

Applicants' arguments have been fully considered but are not deemed persuasive. First, the utility is credible, however, it is not specific or substantial. Although it has been demonstrated in Zhang et al. that TR6 could be used to reduce the symptoms of graft versus host disease in a mouse model, graft versus host disease was one of many different diseases or disorders asserted to be treatable with the protein of the instant invention (provisional application 60/035,496, page 7), and are all diseases or disorders known to involve cytokines and receptors in the TNF family. There was no disclosure of whether the protein could be immune stimulating or immune suppressing. Additionally, provisional application 60/035,496 also attributes the same activities to the TNFR-5 receptor disclosed therein, which is a completely different

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receptor from TR6. Therefore while asserted utility was credible in the earlier applications, it was not specific and substantial. For these reasons the effective priority date is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 24-88 and 102-131 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al., U.S. Patent No. 6,764,679, effective priority date Sept. 18, 1998, for reasons of record in the previous office action, mailed May 9, 2005, at pages 5-6. Since the effective priority date of the instant invention is March 4, 1999, the rejection is maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



EILEEN B. O'HARA
PATENT EXAMINER